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Document Control Office (TS-7407M)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20460

Subject: TSCA 8(e) Submission



Dear Sir/Madam:

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Parametrix, Inc. is submitting preliminary results from an oral reproduction/developmental toxicity screening study in rats to the United States Environmental Protection Agency (USEPA) pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). The study provides information on trichloromethylstannane CAS# 993-16-8.

Parametrix, Inc. is making this submission on behalf of the Organotin Environmental Programme (ORTEP) Association member companies producing trichloromethylstannane in the United States. The managing parties of this international consortium assert on behalf of the sponsoring companies that this notice does not involve effects in humans. It does not contain confidential business information [CBI] under TSCA.

Information below is based on the audited draft report of a 90-day oral study in rats conducted in accordance with OECD guideline 408 with the addition of a satellite group for a reprotoxicity screen as outlined in OECD guideline 421. The test substance is not a material of commerce. It was prepared to accommodate testing of trichloromethylstannane (CAS# 993-16-8) in the High Production Volume program. The material contained approximately 83% trichloromethylstannane, about 9% of dichlorodimethylstannane (CAS# 753-73-1), and the remainder other methyltin compounds.

Groups of 10 male and 10 female rats were administered test substance mixed in feed at 0, 30, 150, 750 mg/kg of diet. During the 90 day study, test substance intake of the male animals averaged 1.9, 9.8 and 49.7 mg/kg body weight/day and in females were 2.1, 10.2 and 53.6 mg/kg body weight/day for the low, mid, and high dose, respectively.

At the high dose, small but statistically significant changes in hematology and clinical chemistry were noted but were not consistent between males and females. Prothrombin time was decreased and

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urinary pH and crystals were increased in high dose males and females. Organ weights changes in the high dose included increased absolute (males, females) and relative (males) adrenal weights, and absolute and relative kidney weights (males, females). Decreases were noted in absolute and relative thymus weights (males, females), absolute and relative brain weights (females), absolute and relative spleen and epididymal weights (males).

Neurobehavioral changes (increased grip strength and landing foot splay in males, and hyperactivity in males and females) and histopathological changes in the thymus (decreased cortex/medulla ration) and brain (loss of perikarya of neuronal cells in the pyramidal layer of the hippocampus) were reported at high dose in both males and females.

The no observed adverse effect level (NOAEL) in this phase of the study is the mid dose, 150 ppm in diet.

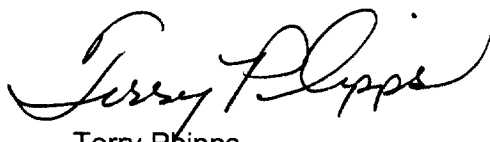
In the satellite group to screen for reprotoxicity, the test substance was administered to females 2 weeks prior to mating with main group males. Test substance intake in females ranged from 1.2 – 2, 6.2 – 9.6, and 35.9 – 45.8 mg/kg body weight/day for the low, mid, and high dose, respectively.

At the high dose, increased post-implantation loss, decreased number of pups delivered, and increased postnatal pup mortality were reported. One high dose dam died (likely due to hemothorax caused by severe dystocia).

The no observed effect level for reproductive and developmental effects and for maternal toxicity in this study is 150 ppm in the diet.

Further questions regarding this submission may be directed to me at (425) 822-8880. Final reports are available to the Office of Pollution Prevention and Toxics upon request.

Best regards,
PARAMETRIX, INC.



Terry Phipps
ORTEP Association
High Production Volume Technical Coordinator

cc: Managing Parties:
ATOFINA Chemicals, Inc.
Crompton Corporation
Rohm and Haas Company